

AMENDED IN SENATE APRIL 12, 2004

**SENATE BILL**

**No. 1623**

---

**Introduced by Senator Johnson**

February 20, 2004

---

~~An act to amend Sections 100700, 100710, 100715, 100720, 100735, 100745, and 100750 of, and to add Sections 100701, 100702, and 100703 to~~ An act to amend Section 100425 of, to add Sections 100701, 100702, and 100703 to, to repeal Sections 100710, 100715, 100720, 100730, 100735, 100740, 100745, 100750, 100755, 100760, 100765, and 100770 of, and to repeal and add Section 100700 of, the Health and Safety Code, relating to laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1623, as amended, Johnson. Laboratories: licensing and accreditation.

*Existing law requires the State Department of Health Services to adopt and publish regulations to be used in approving and governing the operation of laboratories engaging in the performance of tests by or for law enforcement of blood, urine, tissue, or breath samples for the purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations, including the qualifications of the employees who perform the tests, that the department determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests.*

*Existing law requires each laboratory in the state that performs those tests to be licensed by the Director of Health Services. Existing law requires the department to periodically inspect every approved and licensed laboratory. If the director orders the suspension or revocation*

*of a laboratory's license, the licensee is required to surrender the license to the director upon the effective date of that order. Existing law authorizes the director, after suspension of the license, to reinstate the license under prescribed conditions.*

*This bill would repeal all of the above provisions. The bill would instead require laboratories engaging in the performance of forensic alcohol analysis tests on blood, urine, tissue, or breath for the purposes of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations to comply with various existing department regulations regarding inspection of laboratories, collection and handling of samples, methods of analysis, and laboratory records. The bill would prohibit the department from requiring laboratories to be licensed. The bill would require each laboratory to ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation and would require all laboratories to follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board guidelines for proficiency testing.*

*The bill would require the department, on or before July 1, 2005, to establish a review committee that would be required to meet at least once in each 5-year period thereafter, or within 60 days of receipt of a request by the department or a member of the review committee, to evaluate and determine revisions to relevant department regulations. The bill would require the department to adopt the revisions determined by the review committee.*

*The bill would make additional conforming changes to existing law.*

~~Under existing law, the State Department of Health Services is required to adopt and publish regulations to be used in approving and governing the operation of laboratories conducting testing by or for law enforcement agencies of blood, urine, or tissue for the purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations, and the testing of breath samples under the same circumstances.~~

~~This bill would require the department to adopt and publish regulations, that incorporate model specifications published by the National Highway Traffic Safety Administration, to be used in approving and governing the operation of laboratories and law enforcement agencies engaging in breath testing under the~~

circumstances described above. The bill would require the department to convene a review committee, prior to adopting the regulations, and to submit the proposed regulations to the committee for review.

This bill would additionally authorize the performance of the blood, urine, or tissue tests described above by a laboratory holding a current accreditation to perform the test from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). The bill would require the department to issue a license to a laboratory so accredited, and would exempt these laboratories from departmental regulations governing blood, urine, and tissue tests, except with respect to proficiency testing requirements. The bill would establish procedures that permit laboratories accredited by the ASCLD/LAB to appeal the director's determinations. The bill would require the department to accept proof of inspection by the ASCLD/LAB in satisfaction of the department's existing inspection requirement. The bill would make additional conforming changes to existing law.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

1     ~~SECTION 1. Section 100700 of the Health and Safety Code~~  
2     ~~SECTION 1. Section 100425 of the Health and Safety Code is~~  
3     ~~amended to read:~~  
4     100425. (a) The fees or charges for the issuance or renewal  
5     of any permit, license, registration, or document pursuant to  
6     Sections 1639.5, 1676, 1677, 2202, 2805, 11887, ~~100720~~, 100860,  
7     106700, 106890, 106925, 107080, 107090, 107095, 107160,  
8     110210, 110470, 111130, 111140, 111630, 112405, 112510,  
9     112750, 112755, 113060, 113065, 113845, 114056, 114065,  
10    paragraph (2), of subdivision (c) of Section 114090, 114140,  
11    subdivision (b) of Section 114290, 114367, 115035, 115065,  
12    115080, 116205, 117923, 117995, 118045, 118210, and 118245  
13    shall be adjusted annually by the percentage change printed in the  
14    Budget Act for those items appropriating funds to the state  
15    department. After the first annual adjustment of fees or charges  
16    pursuant to this section, the fees or charges subject to subsequent  
17    adjustment shall be the fees or charges for the prior calendar year.  
18    The percentage change shall be determined by the Department of  
19    Finance, and shall include at least the total percentage change in

1 salaries and operating expenses of the state department. However,  
2 the total increase in amounts collected under this section shall not  
3 exceed the total increased cost of the program or service provided.

4 (b) The state department shall publish annually a list of the  
5 actual numerical fee charges for each permit, license, certification,  
6 or registration governed by this section. This adjustment of fees  
7 and publication of the fee list shall not be subject to the  
8 requirements of Chapter 3.5 (commencing with Section 11340) of  
9 Part 1 of Division 3 of Title 2 of the Government Code.

10 *SEC. 2. Section 100700 of the Health and Safety Code is*  
11 *repealed.*

12 ~~100700. The department shall adopt and publish regulations~~  
13 ~~to be used in approving and governing the operation of laboratories~~  
14 ~~engaging in the performance of tests referred to in Sections 100710~~  
15 ~~and 100715, including the qualifications of the employees who~~  
16 ~~perform the tests, that it determines are reasonably necessary to~~  
17 ~~ensure the competence of the laboratories and employees to~~  
18 ~~prepare, analyze, and report the results of the tests.~~

19 *SEC. 3. Section 100700 is added to the Health and Safety*  
20 *Code, to read:*

21 *100700. (a) Laboratories engaged in the performance of*  
22 *forensic alcohol analysis tests on blood, urine, tissue, or breath for*  
23 *the purposes of determining the concentration of ethyl alcohol in*  
24 *persons involved in traffic accidents or in traffic violations shall*  
25 *comply with Group 8 (commencing with Section 1215) of*  
26 *Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California*  
27 *Code of Regulations, as they exist on December 31, 2004, until the*  
28 *time when those regulations are revised pursuant to Section*  
29 *100703.*

30 *(b) Notwithstanding subdivision (a), the department shall not*  
31 *require laboratories to be licensed.*

32 *SEC. 4. Section 100701 is added to the Health and Safety*  
33 *Code, to read:*

34 *100701. Each laboratory shall ensure that breath alcohol*  
35 *instruments and calibrating devices used in testing are listed in the*  
36 *conforming products list in the Federal Register by the National*  
37 *Highway Traffic Safety Administration of the United States*  
38 *Department of Transportation.*

39 *SEC. 5. Section 100702 is added to the Health and Safety*  
40 *Code, to read:*

1 100702. All laboratories shall follow the American Society of  
2 Crime Laboratory Directors/Laboratory Accreditation Board  
3 (ASCLD/LAB) guidelines for proficiency testing.

4 SEC. 6. Section 100703 is added to the Health and Safety  
5 Code, to read:

6 100703. (a) On or before July 1, 2005, the department shall  
7 establish a review committee.

8 (b) The review committee shall have seven members, including  
9 one person representing each of the following:

10 (1) Prosecuting attorneys.

11 (2) Law enforcement agencies.

12 (3) Defense attorneys.

13 (4) Coroners, pathologists, or medical examiners.

14 (5) Criminalists.

15 (6) Toxicologists.

16 (7) Crime laboratory directors.

17 (c) The review committee shall meet at least once in each  
18 five-year period after its initial meeting, or within 60 days of  
19 receipt of a request by the department or a member of the review  
20 committee.

21 (d) The review committee shall evaluate Group 8 (commencing  
22 with Section 1215) of Subchapter 1 of Chapter 2 of Division 1 of  
23 Title 17 of the California Code of Regulations and determine  
24 revisions that will limit those regulations to those that the review  
25 committee determines are reasonably necessary to ensure the  
26 competence of the laboratories and employees to prepare, analyze,  
27 and report the results of the tests and comply with applicable laws.

28 (e) The department shall adopt the review committee's  
29 revisions.

30 SEC. 7. Section 100710 of the Health and Safety Code is  
31 repealed.

32 ~~100710. The testing by or for law enforcement agencies of~~  
33 ~~blood, urine, or tissue for the purposes of determining the~~  
34 ~~concentration of ethyl alcohol in the blood of persons involved in~~  
35 ~~traffic accidents or in traffic violations shall be performed only by~~  
36 ~~a laboratory approved and licensed by the director for the~~  
37 ~~performance of these tests.~~

38 SEC. 8. Section 100715 of the Health and Safety Code is  
39 repealed.

~~100715. The testing of breath samples by or for law enforcement agencies for purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations shall be performed in accordance with regulations adopted by the department.~~

~~The regulations shall establish the procedures to be used by law enforcement agencies in administering breath tests for the purposes of determining the concentration of ethyl alcohol in a person's blood. The regulations shall be adopted and published in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.~~

*SEC. 9. Section 100720 of the Health and Safety Code is repealed.*

~~100720. Each laboratory in the state that performs the tests referred to in Sections 100710 and 100715, shall be licensed by the director. Each of these laboratories, other than a laboratory operated by the state, city or county or other public agency shall upon application for licensing pay a fee to the department in an amount, to be determined by the department, that will reimburse the department for the costs incurred by the department in the issuance and renewal of these licenses. On or before each January 1 of each year thereafter, each of these laboratories shall pay to the department a fee so determined by the department.~~

*SEC. 10. Section 100730 of the Health and Safety Code is repealed.*

~~100730. On or after January 1, 1971, the department shall annually publish a list of approved and licensed laboratories engaging in the performance of tests referred to in Sections 100710 and 100715.~~

*SEC. 11. Section 100735 of the Health and Safety Code is repealed.*

~~100735. Every approved and licensed laboratory shall be periodically inspected by the department. Reports of each inspection shall be prepared on forms furnished by the department and shall be filed with the department.~~

*SEC. 12. Section 100740 of the Health and Safety Code is repealed.*

~~100740. Any license issued pursuant to Section 100720 may be suspended or revoked by the director for any of the reasons set forth in Section 100750. The director may refuse to issue a license~~

1 to any applicant for any of the reasons set forth in Section 100745.  
2 The proceedings under this article shall be conducted in  
3 accordance with Chapter 5 (commencing with Section 11500) of  
4 Part 1 of Division 3 of Title 2 of the Government Code, and the  
5 director shall have the powers and duties granted therein.

6 *SEC. 13. Section 100745 of the Health and Safety Code is*  
7 *repealed.*

8 100745. The director may deny a license if the applicant or  
9 any partner, officer or director thereof:

10 (a) Fails to meet the qualifications established by the  
11 department pursuant to this article for the issuance of the license  
12 applied for.

13 (b) Was previously the holder of a license issued under this  
14 article that was revoked and never reissued or that was suspended  
15 and the terms of the suspension have not been fulfilled.

16 (c) Has committed any act involving dishonesty, fraud, or  
17 deceit whereby another was injured or whereby the applicant has  
18 benefited.

19 *SEC. 14. Section 100750 of the Health and Safety Code is*  
20 *repealed.*

21 100750. The director may suspend, revoke, or take other  
22 disciplinary action against a licensee as provided in this article if  
23 the licensee or any partner, officer or director thereof:

24 (a) Violates any of the regulations adopted by the department  
25 pursuant to this article.

26 (b) Commits any act of dishonesty, fraud, or deceit whereby  
27 another is injured or whereby the licensee benefited.

28 (c) Misrepresents any material fact in obtaining a license.

29 *SEC. 15. Section 100755 of the Health and Safety Code is*  
30 *repealed.*

31 100755. The director may take disciplinary action against any  
32 licensee after a hearing as provided in this article by any of the  
33 following:

34 (a) Imposing probation upon terms and conditions set forth by  
35 the director.

36 (b) Suspending the license.

37 (c) Revoking the license.

38 *SEC. 16. Section 100760 of the Health and Safety Code is*  
39 *repealed.*



~~100760. Upon the effective date of any order of suspension or revocation of any license governed by this article, the licensee shall surrender the license to the director.~~

*SEC. 17. Section 100765 of the Health and Safety Code is repealed.*

~~100765. All accusations against licensees shall be filed within three years after the act or omission alleged as the ground for disciplinary action, except that with respect to an accusation alleging a violation of subdivision (c) of Section 100750, the accusation may be filed within two years after the discovery by the department of the alleged facts constituting the misrepresentation prohibited by that section.~~

*SEC. 18. Section 100770 of the Health and Safety Code is repealed.*

~~100770. After suspension of the license upon any of the grounds set forth in this article, the director may reinstate the license upon proof of compliance by the applicant with all provisions of the decision as to reinstatement. After revocation of a license upon any of the grounds set forth in this article, the license shall not be reinstated or reissued within a period of one year after the effective date of revocation.~~

~~is amended to read:~~

~~100700. The department shall adopt and publish regulations to be used in approving and governing the operation of laboratories engaging in the performance of tests referred to in Section 100710, including the qualifications of the employees who perform the tests, that are determined, pursuant to Sections 100701 and 100703, to be reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests.~~

~~SEC. 2. Section 100701 is added to the Health and Safety Code, to read:~~

~~100701. On or before July 1, 2005, the department shall adopt and publish regulations to be used in approving and governing the operation of laboratories and law enforcement agencies engaging in the performance of the tests referred to in Section 100715 in accordance with the findings of the laboratory directors review panel. The laboratory directors review panel shall be comprised of three California crime laboratory directors, or their designees, including one from the state, one from a county, and one from a~~



1 city. The regulations shall incorporate the Model Specifications  
2 for ~~Evidential Breath Testing Devices and the Model~~  
3 ~~Specifications for Calibrating Units for Breath Alcohol Testers as~~  
4 ~~published in the Federal Register by the National Highway Traffic~~  
5 ~~Safety Administration of the United States Department of~~  
6 ~~Transportation. The revised regulations shall be adopted only after~~  
7 ~~the department has convened a review committee pursuant to~~  
8 ~~Section 100703, and the review committee has determined that the~~  
9 ~~regulations are limited to requirements that the review committee~~  
10 ~~finds are reasonably necessary to ensure the competence of the~~  
11 ~~laboratories or persons conducting the tests.~~

12 SEC. 3. ~~Section 100702 is added to the Health and Safety~~  
13 ~~Code, to read:~~

14 ~~100702. (a) Regulations adopted pursuant to this article~~  
15 ~~governing the tests referred to in Section 100710 shall not apply~~  
16 ~~to a laboratory holding a current accreditation to perform the tests~~  
17 ~~referred to in Section 100710 from the American Society of Crime~~  
18 ~~Laboratory Directors/Laboratory Accreditation Board~~  
19 ~~(ASCLD/LAB). ASCLD/LAB accredited laboratories shall~~  
20 ~~ensure that their published standards, as they relate to proficiency~~  
21 ~~testing, quality control, and inspections, are in compliance with~~  
22 ~~Title 17 of the California Code of Regulations.~~

23 ~~(b) If, at any time, the director determines that standards~~  
24 ~~published by the ASCLD/LAB do not meet the standards~~  
25 ~~contained in the department's regulations, the director shall,~~  
26 ~~within 30 days of making that determination, send a written~~  
27 ~~account itemizing the ways in which ASCLD/LAB standards do~~  
28 ~~not meet those of the department to any laboratory that has~~  
29 ~~presented proof of a current accreditation by the ASCLD/LAB to~~  
30 ~~perform the tests referred to in Section 100710.~~

31 ~~(c) Any laboratory to which a written account of the~~  
32 ~~department's determination is required to be sent pursuant to~~  
33 ~~subdivision (b) may file with the director an objection to that~~  
34 ~~written account within 60 days of the date of issuance of the written~~  
35 ~~account. If an objection is filed pursuant to this subdivision, the~~  
36 ~~director shall, within 60 days of receiving the objection, convene~~  
37 ~~a laboratory directors review panel comprised of three California~~  
38 ~~crime laboratory directors or their designees, including one from~~  
39 ~~the state, one from a county, and one from a city, to resolve the~~  
40 ~~contested issues. The laboratory directors review panel shall~~

1 submit its findings to the director no later than 60 days from the  
2 date of the convening of the panel. The panel's decision shall be  
3 final, and the director shall implement the findings of the panel.

4 ~~(d) Notwithstanding subdivision (a), the department may~~  
5 ~~continue to impose proficiency testing requirements on any~~  
6 ~~laboratory engaging in the performance of tests referred to in~~  
7 ~~Section 100710. All licensed laboratories shall be required to~~  
8 ~~participate in, and pay the fees of, an ASCLD/LAB approved~~  
9 ~~proficiency test program.~~

10 SEC. 4. ~~Section 100703 is added to the Health and Safety~~  
11 ~~Code, to read:~~

12 ~~100703. (a) On or before July 1, 2005, and at least once in~~  
13 ~~each five-year period thereafter, or within 60 days of receipt of a~~  
14 ~~request by a member of the review committee, the department~~  
15 ~~shall convene a review committee to evaluate regulations~~  
16 ~~proposed or adopted by the department pursuant to this article. The~~  
17 ~~review committee shall be selected by the representative agencies,~~  
18 ~~and shall have seven members, including one person representing~~  
19 ~~each of the following:~~

20 ~~(1) Public prosecuting attorneys.~~

21 ~~(2) Law enforcement agencies.~~

22 ~~(3) Public defenders.~~

23 ~~(4) Coroners, pathologists, or medical examiners.~~

24 ~~(5) California Association of Criminalists.~~

25 ~~(6) California Association of Toxicologists.~~

26 ~~(7) California Association of Crime Laboratory Directors.~~

27 ~~(b) The review committee shall examine the regulations~~  
28 ~~adopted by the department pursuant to this article, and recommend~~  
29 ~~revisions that will limit the regulations to requirements the review~~  
30 ~~committee determines are reasonably necessary to ensure the~~  
31 ~~competence of the laboratories and employees to prepare, analyze,~~  
32 ~~and report the results of the test.~~

33 ~~(c) The department shall adopt the revisions recommended by~~  
34 ~~the review committee.~~

35 SEC. 5. ~~Section 100710 of the Health and Safety Code is~~  
36 ~~amended to read:~~

37 ~~100710. The testing by or for law enforcement agencies of~~  
38 ~~blood, urine, or tissue for the purposes of determining the~~  
39 ~~concentration of ethyl alcohol in the blood of persons involved in~~  
40 ~~traffic accidents or in traffic violations shall be performed only by~~

~~a laboratory approved and licensed by the director for the performance of these tests, or by a laboratory holding a current accreditation to perform those tests from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB).~~

~~SEC. 6. Section 100715 of the Health and Safety Code is amended to read:~~

~~100715. The testing of breath samples by or for law enforcement agencies for purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations shall be performed in accordance with regulations adopted by the department pursuant to Section 100701.~~

~~The regulations shall establish the procedures to be used by law enforcement agencies in administering breath tests for the purposes of determining the concentration of ethyl alcohol in a person's blood. The regulations shall be adopted and published in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.~~

~~SEC. 7. Section 100720 of the Health and Safety Code is amended to read:~~

~~100720. Each laboratory in the state that performs the tests referred to in Sections 100710 and 100715, shall be licensed by the director. The director shall issue a license to any laboratory that presents proof of a current accreditation to perform the tests referred to in Section 100710 from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). Each of these laboratories, other than a laboratory operated by the state, city or county or other public agency shall upon application for licensing pay a fee to the department in an amount, to be determined by the department, that will reimburse the department for the costs incurred by the department in the issuance and renewal of these licenses. On or before each January 1 of each year thereafter, each of these laboratories shall pay to the department a fee so determined by the department.~~

~~SEC. 8. Section 100735 of the Health and Safety Code is amended to read:~~

~~100735. (a) Every approved and licensed laboratory shall be available for periodic inspection by the department. Reports of~~

1 each inspection shall be prepared on forms furnished by the  
2 department and shall be filed with the department.

3 (b) The department shall accept proof of inspection by the  
4 American Society of Crime Laboratory Directors/Laboratory  
5 Accreditation Board (ASCLD/LAB), with respect to a laboratory  
6 exempt from departmental regulatory requirements pursuant to  
7 Section 100702, as satisfying the requirements of this section.

8 SEC. 9. Section 100745 of the Health and Safety Code is  
9 amended to read:

10 100745. The director may deny a license if the applicant or  
11 any partner, officer or director thereof:

12 (a) Except as provided in Section 100702, fails to meet the  
13 qualifications established by the department pursuant to this  
14 article for the issuance of the license applied for.

15 (b) Was previously the holder of a license issued under this  
16 article that was revoked and never reissued or that was suspended  
17 and the terms of the suspension have not been fulfilled.

18 (c) Has committed any act involving dishonesty, fraud, or  
19 deceit whereby another was injured or whereby the applicant has  
20 benefited.

21 SEC. 10. Section 100750 of the Health and Safety Code is  
22 amended to read:

23 100750. The director may suspend, revoke, or take other  
24 disciplinary action against a licensee as provided in this article if  
25 the licensee or any partner, officer or director thereof:

26 (a) Except as provided in Section 100702, violates any of the  
27 regulations adopted by the department pursuant to this article.

28 (b) Commits any act of dishonesty, fraud, or deceit whereby  
29 another is injured or whereby the licensee benefited.

30 (c) Misrepresents any material fact in obtaining a license.

31 (d) With respect to a laboratory exempt from departmental  
32 regulatory requirements pursuant to Section 100702, has its  
33 accreditation by the Proficiency Review Committee of the  
34 American Society of Crime Laboratory Directors/Laboratory  
35 Accreditation Board suspended or revoked.